

MAY 09 2013

**510(K) SUMMARY**

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR §807.92.

The assigned 510(k) number is: K122774.

**1. Submitter's Identification:**

**Sakura Seiki Co., Ltd.**  
46-1, Shinden  
Chikuma, Nagano 387-0018  
Japan  
Phone: 81-26-273-3583  
Fax: 81-26-273-2584

Date Summary Prepared: December 5, 2012

**2. Name of the Device:**

Proprietary name:  
**Sakura Steam Sterilizer ASSV-AH06**  
**SKYTRON Integrity 175 Steam Sterilizer**  
**Sakura Steam Sterilizer ASSV-AH06E**  
**SKYTRON Integrity 175 SG Steam Sterilizer**

Common Name: Steam Sterilizer  
Regulation: 21CFR Part 880.6880, Class II  
Product Code: FLE

**3. Common or Usual Name:**

Common name: Steam Sterilizer  
Classification name: Sterilizer, Steam

**4. Predicate Device Information:**

Skytron Integrity 215 Steam Sterilizer, Skytron Integrity 215 SG Steam Sterilizer, K120149

**5. Description:**

Sakura Steam Sterilizer ASSV-AH06, SKYTRON Integrity 175 Steam Sterilizer, Sakura Steam Sterilizer ASSV-AH06E and SKYTRON Integrity 175 SG Steam

Sterilizers are Class II, Product Code FLE Medical Devices as defined by CFR§880.6880 and defined for use in healthcare facilities.

Sakura Steam Sterilizer ASSV-AH06, SKYTRON Integrity 175 Steam Sterilizer, Sakura Steam Sterilizer ASSV-AH06E and SKYTRON Integrity 175 SG Steam Sterilizers provide efficient steam sterilization of non-porous and porous, heat and moisture stable materials. The sterilizers also dry items that have been sterilized with wet steam.

## 6. Intended Use:

Sakura Steam Sterilizer ASSV-AH06 / Skytron Integrity 175 Steam Sterilizer, Sakura Steam Sterilizer ASSV-AH06E / Skytron Integrity 175 SG Steam Sterilizers are designed and optimized for use in health care facilities. Sakura Steam Sterilizer ASSV-AH06 / Skytron Integrity 175 Steam Sterilizer, Sakura Steam Sterilizer ASSV-AH06E / Skytron Integrity 175 SG Steam Sterilizers incorporate high-pressure steam to sterilize non-porous and porous, heat and moisture-stable items and materials used in the health care facilities. Sakura Steam Sterilizer ASSV-AH06 / Skytron Integrity 175 Steam Sterilizer, Sakura Steam Sterilizer ASSV-AH06E / Skytron Integrity 175 SG Steam Sterilizers are available in the following configuration.

17.5" x 17.5" x 26.5" chamber size, Single Door Prevacuum and Gravity.

**Note: Sakura Steam Sterilizer ASSV-AH06E / SKYTRON Integrity 175 SG Steam Sterilizer equip the integrated steam generator.**

Sakura Steam Sterilizer ASSV-AH06 / Skytron Integrity 175 Steam Sterilizer, Sakura Steam Sterilizer ASSV-AH06E / Skytron Integrity 175 SG Steam Sterilizers are equipped with the following factory-programmed sterilization cycle values. The following factory-programmed cycles are validated according to ANSI/AAMI ST8: 2008.

| Cycle             | Maximum Validated Loads   | Sterilize Temp | Sterilize Time | Dry Time |
|-------------------|---|----------------|----------------|----------|
| Flash 1<br>(IU 1) | One unwrapped, nonporous instrument no heavier than 0.22 lbs. (100 gram)  | 270 F (132 C)  | 3 minutes      | 1 minute |
| Flash 2<br>(IU 2) | Maximum of two (2) unwrapped instrument trays, maximum weight 25 pound (11.3 kg) each. The maximum of three (3) 2 mm inside diameter (minimum) and 400 mm | 270 F (132 C)  | 4 minutes      | 1 minute |

|                          |  |               |            |            |
|--------------------------|--|---------------|------------|------------|
|                          | long (maximum) lumen instruments per cycle load.   |               |            |            |
| Prevacuum 270            | Maximum of two (2) double-wrapped instrument trays, maximum weight 25 pound (11.3kg) each. The maximum of three (3) 2 mm inside diameter (minimum) and 400 mm long (maximum) lumen instruments per cycle load.   | 270 F (132 C) | 4 minutes  | 30 minutes |
| Prevacuum 275            | Maximum of two (2) double-wrapped instrument trays, maximum weight 25 pound (11.3 kg) each. The maximum of three (3) 2 mm inside diameter (minimum) and 400 mm long (maximum) lumen instruments per cycle load.  | 275 F (135 C) | 3 minutes  | 30 minutes |
| Express Prevacuum (IU 3) | Maximum of two (2) single wrapped instrument trays, maximum weight 25 pound (11.3 kg) each. The maximum of three (3) 2 mm inside diameter (minimum) and 400 mm long (maximum) lumen instruments per cycle load. This cycle is intended for immediate use and the wrap used for this cycle is not intended to be a sterile barrier. | 270 F (132 C) | 4 minutes  | 3 minutes  |
| Gravity 1                | Maximum of four (4) - fabric packs.  | 250 F (121 C) | 30 minutes | 15 minutes |
| Gravity 2                | Maximum of two (2) double-wrapped instrument trays, maximum weight 25 pound (11.3 kg) each.  | 270 F (132 C) | 15 minutes | 30 minutes |
| Liquid                   | Maximum of three (3) 1,000 mill-liter containers   | 250 F (121 C) | 45 minutes | 0 minutes  |

|                 |   |               |             |           |
|-----------------|---|---------------|-------------|-----------|
|                 | with vented closures. This cycle is intended for non-patient contacting devices only. |               |             |           |
| Leak Test       | Empty Chamber, test time of 15 minutes.   | N/A           | N/A         | N/A       |
| Warm Up         | Empty Chamber   | 270 F (132C)  | 4 minutes   | 3 minutes |
| Bowie-Dick Test | Bowie-Dick Test Pack  | 273 F (134 C) | 3.5 minutes | 2 minutes |

Note:

- "IU" means "Immediate Use Steam Sterilization" cycle.
- Liquid cycle is for non-patient contact use only.

## 7. Technological Characteristics

### Comparison to Predicate Device

The proposed sterilizers offered within this submission are equipped with the same options offered under the predicate device, in design and construction. The only difference between the predicate and the subject device is the size of the models being offered and less number of sterilization cycles. The subject device has different chamber dimensions and different load configurations and less sterilization cycles compared to the predicate device. The predicate devices are larger in size to fit more instruments in one sterilization cycle. This difference has no effect the safety and effectiveness of the device.

### **EFFECTIVENESS:**

Efficacy of sterilizer function and exposure time recommendations are ultimately shown by complete kill of biological indicators and verifying an appropriate safety factor or sterility assurance level (SAL) of at least  $10^{-6}$  reduction. **Sakura Seiki Co., Ltd.** validates its sterilization cycles by recommended practices, standards and guidelines developed by various independent organizations such as the Association for Advancement of Medical Instrumentation (AAMI). Prior to release, the sterilizers were validated to meet the requirements of AAMIANSI ST8: 2008.

The software validation for the cycle operation was performed according to FDA's moderate level of concern recommendations provided in the document *"Guidance for the Content for Premarket Submissions for Software Contained in Medical Devices (May 2005)*.

### **SAFETY:**

Sakura Steam Sterilizer ASSV-AH06, SKYTRON Integrity 175 Steam Sterilizer, Sakura Steam Sterilizer ASSV-AH06E and SKYTRON Integrity 175 SG Steam

Sterilizers have been designed, constructed and tested to meet the safety and performance requirements of various national safety codes and standards. Sakura Steam Sterilizer ASSV-AH06, SKYTRON Integrity 175 Steam Sterilizer, Sakura Steam Sterilizer ASSV-AH06E and SKYTRON Integrity 175 SG Steam Sterilizers comply with the following safety standards:

IEC 60601-1-2:2007

IEC61010-1 (2<sup>nd</sup> Edition) 2008 / CSA C22.2 No.61010-1

IEC61010-2-040: 2005

CISPR11: 2009 ED5.0: AMENDMENT1: 2010

IEC61000-3-2:2005 ED3.0: AMENDMENT1:2010

IEC61000-3-3:2008 ED2.0 (EMC) - PART 3-3

IEC61000-4-2: 2008 ED2.0 (EMC) - PART 4-2

IEC61000-4-3: 2006 ED3.0 +AMENDMENT1: 2007+AMENDMENT2:2010 (EMC)

IEC61000-4-4: 2004 ED2.0 +AMENDMENT1:2010

IEC61000-4-5: 2005 ED2.0

IEC61000-4-6: 2003 ED2.0+AMENDMENT1:2004+AMENDMENT1:2006

IEC61000-4-8: 2009 ED2.0

IEC61000-4-11: 2004 ED2.0

American Society of Mechanical Engineers (ASME) Boiler and Pressure Vessel Code Section VIII Division 1 2010 Edition: Rules for the Construction of Pressure Vessels.

#### **HAZARDS-FAILURE OF PERFORMANCES**

Failure of the sterilization process can lead to incidence of cross contamination, the transmission of potentially infectious organisms from one infected person to another who was not otherwise infected prior to the incident.

To avoid failure, the user must ensure the materials, instruments and devices to be sterilized are thoroughly cleaned, that the manufacturer's instructions for use are followed, that the cycle to be used for each type of sterilizer load has been validated, that the sterilizer has been maintained in accordance with the sterilizer's manufacturer's maintenance schedule and is operating properly, and that each sterilizer load is monitored with available and validated biological and chemical sterilization process indicators.

Today, there are many steam sterilizers in daily use in hospitals throughout the United States. The incident of sterilizer malfunction or sterilization process failure is relatively rare considering the wide spread use of steam sterilizers. Further, there are no reports in the literature of patient infection that have resulted from steam sterilizer failure.

The technology designed in Sakura Steam Sterilizer ASSV-AH06, SKYTRON Integrity 175 Steam Sterilizer, Sakura Steam Sterilizer ASSV-AH06E and SKYTRON Integrity 175 SG Steam Sterilizers provide microprocessor controller safeguards that abort the cycle and give appropriate signals, alerts and warnings when required conditions have not been met or when a malfunction occurs.

## USER INFORMATION

Sakura Seiki Co., Ltd. provides information to the user that is intended to insure safe and effective use of steam sterilization in its detailed User's Manual and other labeling.

Sakura Seiki Co., Ltd. also recommends the use and periodic review of the AAMI steam sterilization standards to ensure further assurance of the safe and effective use of steam sterilization equipment in health care facilities.

### 8. Performance Data:

**Non-clinical:** Verification, validation and testing activities were conducted to establish the performance, functionality and reliability characteristics of Sakura Steam Sterilizer ASSV-AH06, SKYTRON Integrity 175 Steam Sterilizer, Sakura Steam Sterilizer ASSV-AH06E and SKYTRON Integrity 175 SG Steam Sterilizer. The device passed all of the tests based on pre-determined Pass/Fail criteria.

### 9. Conclusions:

The data from consensus standard testing and comparison to the predicate device show that Sakura Steam Sterilizer ASSV-AH06, SKYTRON Integrity 175 Steam Sterilizer, Sakura Steam Sterilizer ASSV-AH06E and SKYTRON Integrity 175 SG Steam Sterilizers are as safe and effective as the legally marketed predicate device.

Therefore **Sakura Seiki Co., Ltd.** conclude that the each of the sterilizers included under this submission are substantially equivalent to the predicate device.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

May 09, 2013

Food and Drug Administration  
10903 New Hampshire Avenue  
Document Control Center – WO66-G609  
Silver Spring, MD 20993-0002

Sakura Seiki Company, Limited  
C/O Ms. Swapna Chirala  
Responsible Third Party Official  
TÜV SÜD America, Incorporated  
1775 Old Hwy 8 NW, Suite 104  
NEW BRIGHTON, MN 55112-1891

Re: K122774

Trade/Device Name: Sakura Steam Sterilizer ASSV-AH06, Skytron Integrity 175 Steam Sterilizer, Sakura Steam Sterilizer ASSV-AH06E Skytron Integrity 175 SG Steam Sterilizer

Regulation Number: 21 CFR 880.6880

Regulation Name: Steam Sterilizer

Regulatory Class: II

Product Code: FLE

Dated: April 4, 2013

Received: April 26, 2013

Dear Ms. Chirala:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.


If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

For  
The handwritten signature is in black ink and appears to read "Anthony D. Watson". It is written in a cursive, flowing style with a large initial "A".

Anthony D. Watson, B.S., M.S., M.B.A.  
Director  
Division of Anesthesiology, General Hospital,  
Respiratory, Infection Control and  
Dental Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure



**Indications for Use Statement**

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**510(k) Number (if known):** K122774

**Device Name:**

Sakura Steam Sterilizer ASSV-AH06  
Skytron Integrity 175 Steam Sterilizer  
Sakura Steam Sterilizer ASSV-AH06E  
Skytron Integrity 175 SG Steam Sterilizer

**Indications For Use:**

Sakura Steam Sterilizer ASSV-AH06 / Skytron Integrity 175 Steam Sterilizer, Sakura Steam Sterilizer ASSV-AH06E / Skytron Integrity 175 SG Steam Sterilizers are designed and optimized for use in health care facilities. Sakura Steam Sterilizer ASSV-AH06 / Skytron Integrity 175 Steam Sterilizer, Sakura Steam Sterilizer ASSV-AH06E / Skytron Integrity 175 SG Steam Sterilizers incorporate high-pressure steam to sterilize non-porous and porous, heat and moisture-stable items and materials used in the health care facilities. Sakura Steam Sterilizer ASSV-AH06 / Skytron Integrity 175 Steam Sterilizer, Sakura Steam Sterilizer ASSV-AH06E / Skytron Integrity 175 SG Steam Sterilizers are available in the following configuration.

17.5" x 17.5" x 26.5" chamber size, Single Door Prevacuum and Gravity.

**Note:** Sakura Steam Sterilizer ASSV-AH06E / SKYTRON Integrity 175 SG Steam Sterilizers equip the integrated steam generator.

**Prescription Use** \_\_\_\_\_ **Over-The Counter Use** X  
(Per 21 CFR 801 Subpart D) OR (21 CFR 807 Subpart C)

**(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)**

\_\_\_\_\_  
**Concurrence of CDRH, Office of Device Evaluation (ODE)**

Elizabeth F. Claverie  
Digitally signed by Elizabeth F. Claverie  
DN: c=US, o=U.S. Government,  
ou=HHS, ou=FDA, ou=People,  
0.9.2342.19200300.100.1.1=130005586  
4, cn=Elizabeth F. Claverie  
Date: 2013.05.08 11:21:20 -04'00'

(Division Sign-Off)  
Division of Anesthesiology, General Hospital  
Infection Control, Dental Devices

**510(k) Number:** K122774

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Sakura Steam Sterilizer ASSV-AH06 / Skytron Integrity 175 Steam Sterilizer,  
 Sakura Steam Sterilizer ASSV-AH06E / Skytron Integrity 175 SG Steam  
 Sterilizers are equipped with the following factory-programmed sterilization cycle  
 values. The following factory-programmed cycles are validated according to  
 ANSI/AAMI ST8: 2008.

| Cycle                          | Maximum Validated Loads   | Sterilize Temp | Sterilize Time | Dry Time   |
|--------------------------------|---|----------------|----------------|------------|
| Flash 1<br>(IU 1)              | One unwrapped, nonporous instrument no heavier than 0.22 lbs. (100 gram)  | 270 F (132 C)  | 3 minutes      | 1 minute   |
| Flash 2<br>(IU 2)              | Maximum of two (2) unwrapped instrument trays, maximum weight 25 pound (11.3 kg) each. The maximum of three (3) 2 mm inside diameter (minimum) and 400 mm long (maximum) lumen instruments per cycle load.      | 270 F (132 C)  | 4 minutes      | 1 minute   |
| Prevacuum<br>270               | Maximum of two (2) double-wrapped instrument trays, maximum weight 25 pound (11.3kg) each. The maximum of three (3) 2 mm inside diameter (minimum) and 400 mm long (maximum) lumen instruments per cycle load.  | 270 F (132 C)  | 4 minutes      | 30 minutes |
| Prevacuum<br>275               | Maximum of two (2) double-wrapped instrument trays, maximum weight 25 pound (11.3 kg) each. The maximum of three (3) 2 mm inside diameter (minimum) and 400 mm long (maximum) lumen instruments per cycle load. | 275 F (135 C)  | 3 minutes      | 30 minutes |
| Express<br>Prevacuum<br>(IU 3) | Maximum of two (2) single wrapped instrument trays, maximum weight 25 pound (11.3 kg) each. The maximum of three (3) 2 mm inside diameter (minimum) and 400 mm long (maximum) lumen instruments per cycle load. | 270 F (132 C)  | 4 minutes      | 3 minutes  |

|                 |  |               |             |            |
|-----------------|--|---------------|-------------|------------|
|                 | This cycle is intended for immediate use and the wrap used for this cycle is not intended to be a sterile barrier.                     |               |             |            |
| Gravity 1       | Maximum of four (4) - fabric packs.  | 250 F (121 C) | 30 minutes  | 15 minutes |
| Gravity 2       | Maximum of two (2) double-wrapped instrument trays, maximum weight 25 pound (11.3 kg) each.  | 270 F (132 C) | 15 minutes  | 30 minutes |
| Liquid          | Maximum of three (3) 1,000 mill-liter containers with vented closures. This cycle is intended for non-patient contacting devices only. | 250 F (121 C) | 45 minutes  | 0 minutes  |
| Leak Test       | Empty Chamber, test time of 15 minutes.  | N/A           | N/A         | N/A        |
| Warm Up         | Empty Chamber  | 270 F (132C)  | 4 minutes   | 3 minutes  |
| Bowie-Dick Test | Bowie-Dick Test Pack   | 273 F (134 C) | 3.5 minutes | 2 minutes  |

**Note:**

- "IU" means "Immediate Use Steam Sterilization" cycle.
- Liquid cycle is for non-patient contact use only.